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EXAMINER

ALBERTALLI, BRIAN LOUIS

ART UNIT

PAPER NUMBER

2655

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/748,660

Applicant(s)

ROWLANDSON ET AL.

Examiner

Brian L. Albertalli

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-14 and 16-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-14 and 16-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed June 23, 2005 have been fully considered but they are not persuasive.

Regarding **claim 18**, the Applicant has argued that Renegar states that the entries listings of words comprise verbs, adjectives, nouns, etc. but Renegar does not teach that there is any actual grammatical characteristic identifier associated with each of the words. However, Renegar discloses that words are grouped according to function (verbs, adjectives, nouns, etc.) and the groupings are used to select words (column 11, lines 25-44) to assemble into a text block (construct sentences). The grouping of words by function acts as a "grammatical characteristic identifier" because it identifies the part of speech of the word.

Regarding **claim 26**, the Applicant has argued that Drucker does not disclose a medical statement library. The thrust of the argument relies on the allegation that the body of medical literature comprised of medical literature references is not a "medical statement library" comprised of "medical statements". However, according to the Applicant's specification, different types of "statements" may include "phrases, sentences, paragraphs, templates, etc.". Given this broad definition of "statements" the Examiner maintains that any collection of words is equivalent to the claimed "statements". Therefore, the body of medical literature disclosed by Drucker is equivalent to a "medical statement library" because each medical literature reference is

a collection of medical words, and thus a “medical statement” as claimed. Further, the selection of a medical reference from the list of references generated from the query is thus equivalent to “selecting a second medical statement” as claimed.

Regarding **claim 30**, the Applicant has argued that data used by Barnhill and disclosed in Fig. 6-9 and column 7, lines 7-11 is not equivalent to the claimed “medical statements” from a “medical statement library”. Again, however, given the Applicants broad definition of what encompasses a “statement”, the examiner maintains that the medical data disclosed by Barnhill is equivalent to the claimed “medical statements”, as each data entry is an expression of the clinical measurements conducted to collect the data.

Regarding **claim 1**, in response to applicant's arguments, the recitation “organizing a statement library” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

As admitted by the Applicant, Chin does disclose associating a part of speech attribute with a plurality of statements. Whether this is used for organizing a statement library is irrelevant, as this limitation is in the preamble of the claim.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Chin discloses associating a part of speech attribute notifies the user of any possible changes or suggestions (column 14, paragraph 0237) and provides a statement including a placeholder, to allow information to be later added (column 11, paragraph 0205 and column 12, paragraphs 0209-0210).

Still further, the teachings of Goltra meet the claims, because, as indicated above, the limitations of organizing a statement library has not been given patentable weight because the recitation occurs in the preamble.

Regarding **claims 10 and 36**, in response to applicant's arguments, the recitation "method of interacting with a cardiographic statement library " has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a

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process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Furthermore, one of ordinary skill in the art of cardiographic statement libraries would be motivated to look at any linguistic literature because the problems associated with cardiographic statement libraries would be the same as those of any statement libraries. That is, the problems encountered in organizing a cardiographic library would be the same as encountered in any textual library.

Still further, regardless of what literature one of ordinary skill in the cardiographic statement library art would look to, nothing in the body of claims 10 or 36 suggest any problems unique to cardiographic libraries may have been solved. Rather, the bodies of claims 10 and 36 are directed to providing keywords and accessing statements associated with the keyword. These steps are not unique to the problems of cardiographic statement libraries; they apply to any general textual library.

Therefore, for the reasons given above, the rejections made in the previous Office Action stand.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claim 18** is rejected under 35 U.S.C. 102(e) as being anticipated by Renegar (USPN 6,024,571).

Regarding **claim 18**, Regenar discloses a method of generating clinical report text, comprising:

accessing a first medical statement from a statement library (figure 3, element 38) the first medical statement including a first grammatical characteristic identifier (allergy; column 14, lines 1-12);

accessing a second medical statement (figure 3, element 38) from the statement library the second medical statement including a second grammatical characteristic identifier (X-ray; column 14, lines 1-12);

accessing the grammatical characteristic identifiers of the first and second medical statements (verbs, adjectives, nouns, etc. column 14, lines 1-12 with column 11, lines 25-44); and

assembling the first medical statement with the second medical statement according to the grammatical characteristic identifiers (column 11 , lines 25-44 with column 14, lines 1-12) of the first medical statement and the second medical statement, into a text block (figure 3, element 38).

**Claims 26-29** are rejected under 35 U.S.C. 102(e) as being anticipated by Drucker et al. (U.S. 6,292,796), hereinafter Drucker.

Regarding **claim 26**, Drucker discloses a method of generating a clinical report through a computer user interface (column 15, lines 53-59 with column 16, lines 9-15), comprising:

selecting a first medical statement from a medical statement library (diagnosis (asthma); column 9, lines 15-25 with electronic medical records system to electronic database or libraries; column 7, lines 30-37);

providing to the user access to a plurality of filtered medical statements (filtering; electronic medical records; column 8, lines 18-34 with column 7, line 37-42) based on the first medical statement, the filter being based on a grammatical characteristic of the first medical statement, a keyword (column 5, lines 47-51 with column 7, lines 51-65); and

selecting a second medical statement from the plurality of filtered medical statements (diagnosis; column 10, lines 60-62 with column 6, lines 29-38).

Regarding **claim 27**, Drucker discloses a method further comprising:

completing automatically a partial identifier entered by a user (column 5, lines 31-36 and column 7, lines 2-6).

Regarding **claim 28**, Drucker discloses a method further comprising:



providing access to the complete statement library upon request by a user and thereby replacing the plurality of filtered medical statements (updated each time; column 7, lines 43-44).

Regarding **claim 29**, Drucker discloses a method further comprising:

providing to the user access to a further filtered list of medical statements derived from the plurality of filtered medical statements based upon a grouping identifier provided by a user (category; column 13, lines 1-7 and lines 23-29).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 30-35** are rejected under 35 U.S.C. 102(b) as being anticipated by Barnhill et al. (USPN 5,769,074), hereinafter referenced as Barnhill.

Regarding **claim 30**, Barnhill discloses a method of making a clinical assessment comprising:

generating a plurality of medical statements from a statement library based on clinical measurements (figures 6-9), at least some of the medical statements in the statement library being associated with a diagnostic predictor (column 7, lines 7-11);

analyzing the diagnostic predictors from the plurality of medical statements (figures 6-9 with column 2, lines 2-23); and

providing, as an output, a clinical assessment based on the analysis of the diagnostic predictors (column 7, lines 7-11).

Regarding **claim 31**, Barnhill discloses a method wherein the plurality of medical statements are automatically generated (column 15, lines 13-14).

Regarding **claim 32**, Barnhill discloses a method further comprising:  
generating a plurality of medical statements based on patient history information with column 12, lines 20-34).

Regarding **claim 33**, Barnhill discloses a method further comprising:  
generating a plurality of medical statements based on physical examination (medical history data; column 7, line 51 information (physical examination; column 12, lines 9-10 with column 20, line 55).

Regarding **claim 34**, Barnhill discloses a method wherein the clinical assessment is a cardiovascular assessment (cardiovascular status', column 12, lines 4-18).

Regarding **claim 35**, Barnhill discloses a method wherein the clinical assessment is a cardiovascular medical statement (cardiovascular status; column 12, lines 4-18).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1-2, 8-9, 10-11, 16-17 and 36-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goltra (USPN 5,823,949) in view of Chin et al (US Publication No. 2001/0029455), hereinafter referenced as Chin.

Regarding **claims 1, 10, and 38**, Goltra discloses a method of organizing, interacting and searching a statement library, the statement library (computer based medical system; column 3, lines 5-8) including a plurality of statements (diagnoses: coronary artery stenosis, angina pectoris, etc.; column 5, lines 39-46) each statement having statement text (a cough; column 3, lines 31-33), a statement number (findings assigned a number; column 3, lines 37-40), and a statement acronym (SYM-symptoms section; column 3, lines 42-44), the method comprising:

- associating each statement (diagnoses) to at least one statement grouping (divided into categories; column 3, lines 26-29);

- associating each statement (a cough) to a plurality of statement attributes (second level; brassy cough etc.);

- associating keywords (code) to at least one of statement groupings (column 3, lines 37-51), and statement numbers (column 3, lines 37-40); and

- associating each statement with other statements (first level, second level; column 3, lines 31-40), but lacks associating a part of speech attribute with a plurality of statements and providing a statement including a placeholder.

Chin discloses a method of organizing a statement library comprising:

associating a part of speech attribute with a plurality of statements (part-of-speech tags; column 14, paragraphs 0237 and 0241), to check to see if any unlikely tag sequences are detected; and

providing a statement including a placeholder (column 11, paragraph 0205), to hold places where information should be entered later.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goltra's method wherein it associates a part of speech attribute with a plurality of statements, to notify the user of any possible changes or suggestions (column 14, paragraph 0237) and wherein it provides a statement including a placeholder, to allow information to be later added (column 11, paragraph 0205 and column 12, paragraphs 0209-0210).

Regarding **claims 2 and 16**, Goltra discloses a method further comprising:  
providing placeholders (assigned a numerical value) in a plurality of statements (column 3, lines 56-59).

Regarding **claim 8**, Goltra discloses a method further comprising:  
associating an acronym with a plurality of statements (SYM, HIS, PHY, column 3, lines 40-51).

Regarding **claim 9**, Goltra discloses a method further comprising:  
associating a diagnostic predictor with a plurality of statements (column 5, lines 32-56).

Regarding **claims 11 and 37**, Goltra discloses a method further comprising:

accessing a minor grouping (a cough) associated with the grouping (column 3, lines 26-36).

Regarding **claim 17**, Goltra discloses a method further comprising:

providing abbreviated statement text (SYM, HIS, PHY, column 3, lines 40-51).

Regarding **claim 36**, Goltra discloses a method of searching a statement library comprising:

generating a plurality of medical statements based on physical examination information (physical examination; column 4, lines 48-51).

providing at least one search keyword (SYM; column 3, lines 37-51);

accessing a statement grouping associated with the keyword (column 3, lines 37-51); and

providing a listing of reports associated with the statements of the grouping (column 4, lines 20-27).

**Claims 3-5 and 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goltra in view Chin, as applied to claims 1 and 10 above, and in further view of Drucker.

Regarding **claims 3 and 12**, Goltra in view of Chin discloses a method of organizing, interacting and searching a statement library, the statement library, but lacks enabling user initiated changes in font within each statement.

Drucker does not specifically teach enabling user initiated changes in font within each statement, but teaches that a user setup is incorporated within the medical records system (column 6, lines 55-65).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goltra in combination with Chin's invention such that it enables a user to initiate changes in font within each statement, so that any important information, new diagnosis, changes in the system or the like, could stand out from other information, which is well known in the art.

Regarding **claims 4 and 13**, Goltra in view of Chin discloses a method of organizing, interacting and searching a statement library, the statement library, but lacks a method comprising

providing reference information in a plurality of statements.

Drucker discloses a statement library further comprising:

providing reference information (medical journals) in a plurality of statements (column 6, line 63- column 7, line 6 and column 7, lines 27-33), to learn more about a certain type of illness, to handle a patient with unfamiliar symptoms, etc.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goltra in combination with Chin's invention such that it provides reference information in a plurality of statements, to learn more about a certain type of illness, to handle a patient with unfamiliar symptoms which will relieve some of the time constraints placed on physicians time (column 1, lines 8-24).

Regarding **claims 5 and 14**, Goltra in view of Chin discloses a method of organizing, interacting and searching a statement library, the statement library, but lacks a method comprising providing a hyperlink in a plurality of statements.

Drucker discloses the method comprising:

providing a hyperlink in a plurality of statements (column 10, lines 12-14), to enable a user to access an internet website quickly.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goltra in combination with Chin's invention such that it provides a hyperlink in a plurality of statements, to learn more about information needed in less time (column 1, lines 8-24).

**Claims 19-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Renegar in view of Goltra.

Regarding **claim 19**, Renegar discloses a method for generating a clinical report but lacks, associating measurement data with the first medical statement.

Goltra discloses a method further comprising:

associating measurement data (assigned value) with the first medical statement (medical findings; column 3, lines 65-67), to have a detailed explanation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Renegar's method associating measurement data with the first medical statement, to help healthcare professional create medical protocols or assist with direct entry (column 1, lines 7-13).

Regarding **claim 20**, Renegar discloses a method for generating a clinical report but lacks, incorporating reason codes into the text block.

Goltra discloses a method further comprising:  
incorporating reason codes into the text block (diagnoses are coded; column 4, lines 13-19), to uniquely identify the medical findings.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Renegar's method incorporating reason codes into the text block, to help healthcare professional create medical protocols or assist with direct entry (column 1, lines 7-13).

Regarding **claim 21**, Renegar discloses a method for generating a clinical report but lacks, associating the first and second medical statements with a template configured to guide assemblage of the text block.

Goltra discloses a method further comprising:  
associating the first and second medical statements with a template configured to guide assemblage of the text block (hierarchical levels; column 3, lines 29-36), to give the medical explanations in different levels of details.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Renegar's method associating the first and second medical statements with a template configured to guide assemblage of the text block, to help healthcare professional create medical protocols or assist with direct entry (column 1, lines 7-13).



Regarding **claim 22**, Renegar discloses a method for generating a clinical report but lacks, constraining selection of the second medical statement according to a template configured to guide assemblage of the text block.

Goltra discloses a method further comprising:

constraining selection of the second medical statement according to a template configured to guide assemblage of the text block (hierarchical levels; column 3, lines 29-36), to give the medical explanations in different levels of details.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Renegar's method constraining selection of the second medical statement according to a template configured to guide assemblage of the text block, to help healthcare professional create medical protocols or assist with direct entry (column 1 , lines 7-13).

Regarding **claim 23**, Renegar discloses a method for generating a clinical report but lacks, constraining the selection of the second medical statement from a specific grouping according to the template.

Goltra discloses a method further comprising:

constraining the selection of the second medical statement from a specific grouping (symptoms) according to the template (column 5, lines 57-67), to provide a list of other symptoms from the top selected diagnoses generated by the intelligent prompting feature.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Renegar's method constraining the selection of

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the second medical statement from a specific grouping according to the template, to allow multiple people to use the medical system for the same or multiple patients (column 3, lines 20-22).

Regarding **claim 24**, Renegar discloses a method for generating a clinical report but lacks, constraining the selection of the second medical statement according to the grammatical characteristics of the third medical statement as specified in the template

Goltra discloses a method further comprising:

constraining the selection of the second medical statement according to the grammatical characteristics of the third medical statement as specified in the template (hierarchical levels; column 3, lines 29-36), to give the medical explanations in different levels of details.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Renegar's method constraining the selection of the second medical statement according to the grammatical characteristics of the third medical statement as specified in the template, to help healthcare professional create medical protocols or assist with direct entry (column 1, lines 7-13).

Regarding **claim 25**, Renegar discloses a method for generating a clinical report but lacks, constraining the selection of the second medical statement according to an explicit statement list as specified by the template.

Goltra discloses a method further comprising:

constraining the selection of the 'second medical statement according to an explicit statement (symptoms) list as specified by the template (column 5, lines 57-67),

to provide a list of other symptoms from the top selected diagnoses generated by the intelligent prompting feature.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Renegar's method constraining the selection of the second medical statement according to an explicit statement list as specified by the template, to allow multiple people to use the medical system for the same or multiple patients (column 3, lines 20-22).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Albertalli whose telephone number is (571) 272-

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7616. The examiner can normally be reached on Mon - Fri, 8:00 AM - 5:30 PM, every second Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wayne Young can be reached on (571) 272-7582. The fax phone number for the organization where this application or proceeding is assigned is ~~703-872-9306~~ <sup>571-273-8300</sup>.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BLA 8/24/05

W. A. YOUNG  
PRIMARY EXAMINER